Product data sheet

- for PU3033AH


## a) General description

| Item | Description |
| :--- | :--- |
| Product name | Medical Video Endoscope |
| Trade name | Uscope |
| Common name | Single Use Flexible Video Ureteroscope |
| Model | PU3033AH |
| use | This instrument has been designed to be used with Endo-Therapy <br> accessories such as a biopsy forceps and other ancillary <br> equipment for endoscopy and endoscopic surgery within urinary <br> tract and interior of the kidney. <br> Intended <br> Indications for use environment: The endoscope is for use in a hospital or <br> qualified medical institution. |
| Intended users | This endoscope is only to be used by skilled physicians trained in <br> clinical endoscopic techniques and procedures. |
| Risk class | Class Ila - per Rule 5 of Annex VIII of Regulation (EU) 2017/745. |
| Shelf life | 3 years. |
| GMDN code | 64074 (GMDN Term: Flexible video ureteroscope, single-use) |
| Characteristics | sterilized by EO, provided sterile, for single use. |
| Models of compatible <br> image processor of <br> Pusen | PV300. |
| Manufacturer | Zhuhai Pusen Medical Technology Co., Ltd. <br> Address: 5/F, Building 1, No 33, Keji San Road, High-tech Zone, <br> Tangjiawan Town, 519085 Zhuhai, Guangdong, PEOPLE'S <br> REPUBLIC OF CHINA. |

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b) Technical specifications

| Items | PU3033AH |
| :---: | :---: |
| Field of view | $120^{\circ} \pm 10 \%$ |
| Direction of View | $0^{\circ} \pm 10^{\circ}$ |
| Depth of field | $3-50 \mathrm{~mm}$ |
| Distal end diameter | $2.5 \mathrm{~mm}(7.5 \mathrm{Fr})$ <br> [limit deviation is $+5 \%$; lower limit is excluded] |
| Diameter of insertion portion | $2.5 \mathrm{~mm}(7.5 \mathrm{Fr})$ <br> [limit deviation is $+5 \%$; lower limit is excluded] |
| Maximum insertion portion width | $\leq 2.7 \mathrm{~mm}$ |
| Minimum instrument channel width | $\geq 1.2 \mathrm{~mm}$ ( $\geq 3.6 \mathrm{Fr}$ ) |
| Working length | $650 \mathrm{~mm} \pm 10 \%$ |
| Bending section | $270^{\circ}$ up/down <br> (limit deviation is $-15^{\circ}$, upper limit is excluded.) |
| Total length | 915 mm |
| illumination | LED |
| Shelf life | 3 years. |
| Model(s) of compatible image processor | PV300. |

## c) Environment specifications

| Operating Environment |  |
| :--- | :--- |
| Temperature | $10^{\circ} \mathrm{C} \sim 37^{\circ} \mathrm{C}$ |
| Relative humidity | $30 \% \sim 85 \%$ |
| Atmospheric pressure | $800-1060 \mathrm{hPa}$ |
| Storage and transportation |  |
| Storage temperature | $0^{\circ} \mathrm{C}$ to $45^{\circ} \mathrm{C}$ |
| Transportation temperature | $-20^{\circ} \mathrm{C}$ to $45^{\circ} \mathrm{C}$ |
| Storage and transportation relative humidity | $30 \% \sim 80 \%$ |

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## d) Key functional elements


(1) Buttons (user-defined buttons): functions of the buttons can be set by compatible image processor.
(2) Locking valve (Instrument channel port): used for the insertion of EndoTherapy accessories.
(3) Luer connector cap: used to seal the (4) Irrigation port.
(4) Luer connector (Irrigation port): used for liquid irrigation.
(5) Insertion portion.
(6) Distal tip.
(7) Bending section (controllable portion).
(8) Supply connector (supply cable connector): data transmission with image processor.
(9) Bending control lever (deflection lever): by sliding this lever back or forth, the bending direction and angle of the bending section can be controlled.
(10) Suction valve: activates suction when pressed down.
(11) Suction connector: used to connect negative pressure device.
(12) Connecting tube (type reference: 1.12.00027): used to connect the (4) Irrigation port with the irrigation system.

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## e) Principles of operation

The Medical Video Endoscope PU3033AH needs to be connected with the HD Medical Video Endoscope Image Processor (model: PV300) as a Medical Video Endoscope System.

The Medical Video Endoscope system is designed to provide image solution for endoscopy and endoscopic surgery, and perform procedures within urinary tract and interior of the kidney by using appropriate Endo-Therapy accessories.

